



Department of Pharmaceutical Services
Ministry of Health
Brunei Darussalam

GUIDELINES FOR NOTIFICATION OF COSMETIC PRODUCTS IN BRUNEI DARUSSALAM



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BACKGROUND

ASEAN Harmonised Cosmetic Regulatory Scheme

1. On 2 September 2003, the Ministers of Trade & Industry of ASEAN Member Countries signed the ASEAN Harmonised Cosmetic Regulatory Scheme (AHCRC) which lays down the requirements in the ASEAN Cosmetic Directive (ACD) for cosmetic products for all signatory ASEAN Member States with effect from 1 January 2008.
2. A cosmetic product produced or marketed in any ASEAN Member States and meets the requirements of the ACD would be able to enter other ASEAN Member States. With the implementation of the ACD, regulatory control of cosmetic products moved from pre-marketing approval to post-marketing system and "post-marketing surveillance".

INTRODUCTION

Cosmetic Product Notification Procedure

3. Cosmetic products in Brunei Darussalam are regulated by the Medicines (Cosmetic Products) Regulations, 2007 (the Regulations), which is in line with the ACD.
4. The Brunei Darussalam Medicines Control Authority (BDMCA) through the Director of Pharmaceutical Services is the Authority for the implementation of the Regulations in Brunei Darussalam. On 3 June 2008, with the commencement of the Regulations, all importers or manufacturers must notify the Authority before placing the cosmetic product in the local market. All cosmetic products must comply with the Regulations by 1 January 2011.
5. Cosmetic Product Notification involves an upfront declaration of compliance by the importer or manufacturer before placing the cosmetic product in the local market. Cosmetic products can only be marketed after receiving the notification acknowledgement letter from the Authority.
6. It is an offence under the Regulations if the importer or manufacturer:
 - fails to notify the Authority prior to importation or manufacture of the cosmetic product
 - provides false or misleading information to the Authority
7. The validity period for the notification is either one year or 2 years or 3 years and the importer or manufacturer must renew their cosmetic product notification should he wishes to continue to market their cosmetic product in Brunei Darussalam.

OBJECTIVE

8. The guidelines describe the requirements for notification procedure, and the responsibility of the importer or manufacturer of a cosmetic product as stipulated in the Regulations.

DEFINITION OF COSMETIC PRODUCT

9. "Cosmetic product" means any substance or preparation intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view

exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition or all or any of those purposes.

[See Appendix 1 for Illustrative List of Cosmetic Products (list is not exhaustive)]

Product Presentation(s)

10. The following are the explanations of the various presentation types of cosmetic products:
 - i. "A single product" exists in a single presentation form.
 - ii. ¹ "A range of variants similar in composition for the same use but differs in colours, flavours etc." is a range of cosmetic products, which are similar in composition and produced by the same manufacturer, and are intended for the same use but are available in different shades of colours (e.g. lipstick, eye shadows or nail polish but not composite pack of different types).
 - iii. ¹ "Palette(s) in a range of one product type" refers to a range of colours as defined above, which may be presented in a series of palettes.
 - iv. ¹ "Combination product in a single kit" refers to similar and/or different product types packed and sold in a single kit. They cannot be sold separately (e.g. a make-up kit of eye and lip colours; a set of skin care products sold in a single kit).

¹ For these presentation types, only one notification form is required to be submitted.

Cosmetic Product Classification

11. Cosmetic products are classified into 3 categories:
 - i. **High Risk**
 - a) Cosmetic products for application on the region around the eye, including eye creams, eye shadows, eyeliners and mascaras.
 - b) Cosmetic products for application on the lips, including lipsticks, lip colours and lip creams.
 - c) Oral or dental hygiene products, including mouth refreshers and dentifrices.
 - d) Hair dyes containing phenylenediamines; their N-substituted derivatives and their salts; diaminophenols
 - ii. **Medium Risk**

Leave-on cosmetic products i.e. for applications on the hair, scalp, skin, nails without rinsing.
 - iii. **Low Risk**

Rinse-off cosmetic products i.e. for application on the hair, scalp, skin or nails which remain in traces after rinsing or use.

Contents Of Cosmetic Products

12. Cosmetic products must not contain the following ingredients/substances:
- i. Substances listed in Part I of the First Schedule to the Regulations and/or the latest amendments in Annex II of the ACD unless its presence is in trace amounts and is technically unavoidable in good manufacturing practice;
 - ii. Substances in concentrations beyond the limits and outside the conditions laid down in Part II of the First Schedule to the Regulations and/or the latest amendments in Annex III Part 1 of the ACD;
 - iii. Substances which are present after the allowable deadline as listed in the List of Substances Provisionally Allowed in Part II of the First Schedule to the Regulations and/or the latest amendments in Annex III Part 2 in the ACD;
 - iv. Colouring agents other than those listed in Part III of the First Schedule to the Regulations and/or the latest amendments in Annex IV of the ACD;
 - v. Colouring agents used outside the limitations and requirements laid down in Part III of the First Schedule to the Regulations and/or the latest amendments in Annex IV of the ACD;
 - vi. Preservatives other than those listed in Part IV of the First Schedule to the Regulations and/or the latest amendments in Annex VI of the ACD;
 - vii. Preservatives agents used beyond the limits and outside the conditions laid down in Part IV of the First Schedule to the Regulations and/or the latest amendments in Annex VI of the ACD;
 - viii. UV Filters not listed in Part V of the First Schedule to the Regulations and/or the latest amendments in Annex VII of the ACD;
 - ix. UV Filters in concentrations beyond the limits and outside the conditions laid down in Part V of the First Schedule to the Regulations and/or the latest amendments in Annex VII of the ACD.

WHO SHOULD NOTIFY?

Importer/Manufacturer

13. The importer or manufacturer of the cosmetic products in Brunei Darussalam must notify the Authority before placing the cosmetic product in the local market using the prescribed Cosmetic Product Notification Form. The cosmetic product can only be marketed after receiving the notification acknowledgement letter from the Authority.

Requirement for Importer/Manufacturer

14. The importer, if he is an individual, must be registered under the Business Names Act (Chapter 92) and must hold a Brunei Darussalam Identity Card and be based in Brunei Darussalam, possesses adequate knowledge and complies with all regulations specified by the Authority.
15. The importer may appoint a representative. The representative must hold a Brunei Darussalam Identity Card and be based in Brunei Darussalam, possesses adequate knowledge and complies with all regulations specified by the Authority.
16. The importer, if it is a company must be incorporated and registered under the Companies Act (Chapter 39).
17. The manufacturer must comply with the ASEAN Guidelines on Good Manufacturing Practice (GMP) for cosmetics.

Additional duties

18. The importer or manufacturer must -
- i. keep the product's technical and safety information i.e. Product Information File (PIF) readily accessible to the Authority for auditing purposes;
 - ii. keep records of importation, distribution and sale of the cosmetic products ready for auditing purposes;
 - iii. have proper complaints management procedures and reporting of defects and adverse events to the Authority;
 - iv. ensure that their cosmetic product complies with the safety and quality requirements;
 - v. ensure that each consignment of the product meets the requirements of the Authority and will not cause damage to human health under normal or reasonably foreseeable conditions of use.

HOW TO NOTIFY?

Notification Procedure

19. The cosmetic product notification form can be obtained from the Cosmetic Unit or can be downloaded from the following website:
<http://www.moh.gov.bn/medhealthservices/pharmacyservices.htm>

Documents Required To Be Submitted

20. Completed cosmetic product notification form.
21. The following documents must be submitted with the first notification:
- i. A copy of the company's certificate of incorporation;
 - ii. A copy of the importer's and representative's (if applicable) Brunei Darussalam Identity Card; and
 - iii. Letter of authorization for the appointed representative(s), if applicable.

Filling In Notification Form

22. A single notification form must be submitted for each cosmetic product.
23. A single notification form may be submitted for cosmetic products in a palette. However, full ingredient listing (list the colorants used in each product that form the palette) will have to be declared for each colour and product type (e.g. eyeshadow, blusher etc.). A new notification is required to be submitted for colours that are not included in the initial notification.
24. A single notification form may be submitted for a combination of cosmetic products in a single kit. However, full ingredient listing will have to be declared for each cosmetic product in the combination kit.

25. A single notification form may be submitted for a product with the same brand/product name, product type, formulation, intended use and presentation from more than one manufacturers/contract manufacturers and /or assemblers from the same country of origin.
26. A single notification form may be submitted for variants of a cosmetic product with the same brand and product name, product type, intended use and manufacturers/contract manufacturers and /or assemblers.

Submitting Notification Form

27. The Cosmetic Product Notification Form shall be submitted only ONCE for each cosmetic product.
28. Completed forms shall be submitted to the Cosmetic Unit, Drug Administration Section, Department of Pharmaceutical Services, Ministry of Health located at Spg 433, Lebuhraya Rimba, Kg. Madaras, Mukim Gadong 'A', Brunei Darussalam.
29. Each cosmetic product application form would be issued with temporary reference numbers (...) Not.Form/CU/20__ which would be used for all correspondences before the notification numbers are issued.

Acknowledgement Of Cosmetic Product Notification

30. Each product notification form submitted shall be acknowledged within 3 working days, and a cosmetic product notification number would be issued for each cosmetic product. Incomplete information may cause unnecessary delay in acknowledgement of the notification.
31. Acceptance of a product notification does not constitute, in any way, an agreement that the product meets all the regulatory requirements.
32. Each notification would be valid for one year, 2 years or 3 years.

Renewal of Cosmetic Product Notification

33. Application Form(s) for renewal of cosmetic product notifications must be submitted 2 weeks before the expiry of the validity period of the cosmetic product notification acknowledgement letter. These form(s) must be submitted together with the respective original Letter of Acknowledgement of the Cosmetic Product Notification.

Amendments In Particulars Of Notified Cosmetic Products

34. Any subsequent amendments in particulars of the notified cosmetic products must be informed to the Authority. Some of the types of changes to particulars of notified cosmetic product and the subsequent requirement are listed below:

No.	Types of Changes	Product Notification
1	Brand name	New
2	Company change due to change of distribution rights	New
3	Product types	New
4	Product presentation (single product, palettes in a range, etc)	Amendment
5	Intended use	New
6	Product name	New
7	Formulation	New
8	Manufacturer and/or assembler (name and/or address) including addition of a new manufacturer and/or assembler.	New
9	Name and/or address of local company without change of distribution rights	Amendment
10	Person representing local company	Amendment
11	Importers including the addition of new importers.	Amendment

NOTIFICATION FEES

35. A notification fee is payable for each cosmetic product **upon submission** of the notification form.

The fees are shown in the following table:

Fees for Notification of Cosmetic Products			
(1)	(a)	New Product Notification	\$10/ year
	(b)	Product variant	\$10/ year
	(c)	Palette(s) in a range of one product type	\$10 each (first 5 colours)/ year \$5 each (subsequent colour)/ year
(2)	Renewal of Cosmetic Product Notification*		\$10/ year
(3)	Application to amend Cosmetic Product Notification		No charge

*Renewal of Cosmetic Product Notification – Annual renewal fee to maintain the notification of each cosmetic product.

LABELLING REQUIREMENTS

Labelling Of Cosmetic Products

36. The following information must be on the outer packaging or, when there is no outer packaging, on the immediate packaging of the cosmetic product :

- i. Name and function of product;
- ii. Instructions on the use (unless clearly indicated from the product name);
- iii. Full ingredient listing using INCI names, and CI number for colorants (if applicable);
- iv. Country of Manufacture;
- v. Name & Address of company responsible for putting cosmetic product on the local market;
- vi. Contents by weight or volume in either metric or both metric and imperial system;
- vii. Manufacturer's batch number;
- viii. Manufacturing or expiry date;
- ix. Special precautions as stated in Parts II, III IV and V of the First Schedule to the Regulations (if applicable).

Note: The label must be prominently and conspicuously displayed on the cosmetic product at the point of sale. Where the size, shape or nature of the container or package does not permit all the required information to be specified on the container or package, the use of leaflets, pamphlets, hang tags, display panels etc. are allowed. However, the name of the cosmetic product and the batch reference must be displayed on the container or immediate package.

37. The ingredients of the cosmetic product should be listed in descending order by concentration (%w/w, %w/v or %v/v).
38. There must be a statement (of any format) on the cosmetic product label to indicate the presence of ingredients of animal origin, in particular of porcine origin.

Language

39. Information on the cosmetic product label must be in the English and/or Malay language or both and must be legible, comprehensible and indelible. Other languages, if any, may be present on the label.

Non-permissible Claim For Cosmetics

40. All claims must comply with the Regulations and the ASEAN Claim Guidelines;
 - i. Labelling and advertising of cosmetic products, text names, trademarks, pictures and figurative or other must not imply that these cosmetic products have characteristics which they do not have;
 - ii. Claims with therapeutic benefit or can be used for a therapeutic purpose or which is likely to create an erroneous impression regarding the formulation, composition, quality or safety of the cosmetic product are not permitted.

POST-MARKETING SURVEILLANCE

Product Recall

41. The Authority may direct that a cosmetic product be withheld from sale and supply, and withdrawn from the market if the product is suspected or found to cause damage to human health when applied under normal or reasonably foreseeable conditions of use.

Suspension And Cancellation Of Product Notification

42. The Authority has the right to suspend or cancel any Cosmetic Product Notification if the cosmetic product is suspected and / or found to cause damage to human health when applied under normal or reasonably foreseeable conditions of use.

REPORTING OF ADVERSE EVENTS

43. The supplier (importer or manufacturer) must have proper complaints management procedures that include answering to the consumer, investigating the cause and determining the frequency of any adverse event. The supplier must report;
 - i. any serious adverse events to the Authority within 15 days after first knowledge of the event;
 - ii. fatal or life threatening events within 7 days after first knowledge of the event, followed by a detailed report within 8 calendar days of the initial report. Non serious reactions include irritations or allergies need not be reported, but they need to be recorded internally as complaints.
44. Adverse events report forms can be downloaded from the website below and the completed form shall be submitted to the Cosmetic Unit in accordance to the criterias listed in item 43.

PENALTY

45. Any person who contravenes any provision of the Regulations, if found guilty, is liable on conviction to a fine of not exceeding \$5000, imprisonment term of not more than 2 years or both.

ENQUIRY

46. All enquiries on cosmetic products should be directed to:

Cosmetic Unit,
 Drug Administration Section,
 Department of Pharmaceutical Services,
 Ministry of Health,
 Spg 433, Lebuhraya Rimba, Kg. Madaras, Mukim Gadong 'A'
 Brunei Darussalam.
 E-mail: cosmetic@moh.gov.bn
 Tel: (673) 2393298, (673) 2393301 (673) 2393230 ext 218
 Fax: (673) 2393297

47. Information on the ASEAN Cosmetic Directive requirements and other relevant documents can be found under the following website:

<http://www.moh.gov.bn/medhealthservices/pharmacyservices.htm>

1. "importer", in relation to a cosmetic product, means any person who imports or who procures or arranges for the import of any cosmetic product into Brunei Darussalam for supply in Brunei Darussalam
2. "manufacturer" means any person engaged in any process carried out in the course of making any cosmetic product in Brunei Darussalam for supply in Brunei Darussalam
3. "label", means any written, printed or graphic representation that appears on or is attached to the cosmetic product or any part of its packaging, and includes any informational sheet or leaflet that accompanies the cosmetic product when it is being supplied
4. INCI – International Nomenclature of Cosmetic Ingredients
5. CAS – Chemical Abstract Services

Appendix 1: Illustrative List Of Cosmetic Products

- Creams, emulsion, lotions, gels and oils for the skin (hands, face, feet, etc)
- Face masks (with the exception of chemicals peeling products)
- Make-up powders, after-bath powders, etc
- Toilet soaps, deodorant soaps, etc
- Perfumes, toilet waters and eau de Cologne
- Bath and shower preparations
- Depilatories
- Deodorants and anti-perspirants
- Hair care products (hair tints, bleaches, cleansing products i.e shampoo, conditioning products, hairdressing products)
- Shaving products
- Make-up products and make-up removal products
- Products intended for application to lips
- Products for care of the teeth and mouth
- Products for nail care and make-up
- Products for external intimate hygiene
- Sunbathing, tanning products
- Skin-whitening products
- Anti-wrinkle products

(above list is not exhaustive)

Appendix 2: Diagrammatic Information on Product Presentation Types

- Single products exists in a single presentation form



- A range of variants is similar in composition for the same use but differs in colours, flavours etc. is a range of cosmetic products, which are similar in composition and produced by the same manufacturer, and are intended for the same use but are available in different shades of colours (e.g. lipstick, eye shadows or nail polish but not composite pack of different types).



- Palette may consist of a range of one product type refers to a range of colours as defined above, which may be presented in a series of palettes.



- Combination product in a single kit refers to similar and/or different product types packed and sold in a single kit. They cannot be sold separately (e.g. a make-up kit of eye and lip colours; a set of skin care products sold in a single kit).



Appendix 3: ASEAN Cosmetic Labelling Requirements

A. OBJECTIVE

1. This document provides guidance for the labelling requirements of cosmetic products to which Article 6 of the ASEAN Cosmetic Directive 05/01/ACCSQPWG apply.

B. SCOPE AND DEFINITIONS

1. For the purpose of this document:

Name of the cosmetic product means the name given to a cosmetic product, which may be an invented name, together with a trade mark or the name of the manufacturer;

Immediate packaging means the container or other form of packaging immediately in contact with the cosmetic product;

Outer packaging means the packaging into which is placed the immediate packaging;

Labeling means information written or printed or graphic matter on the immediate or outer packaging and any form of leaflets;

C. LABELLING OF COSMETIC PRODUCTS

1. The following particulars shall appear on the outer packaging of cosmetic products or, where there is no outer packaging, on the immediate packaging of cosmetic products:
 - a) The name of the cosmetic product and its function, unless it is clear from the presentation of the product;
 - b) Instructions on the use of the cosmetic product, unless it is clear from the product name or presentation;
 - c) Full ingredient listing. The ingredients must be declared in descending order of weight at the time they are added. Perfume and aromatic compositions and their raw materials may be referred to by the word "perfume", "fragrance", "aroma" or "flavour".

Ingredients in concentrations of less than 1% may be listed in any order after those of concentration of more than 1%. Colouring agents may be listed in any order after the other ingredients, in accordance with the colour index number or denomination adopted in Annex IV.

For decorative cosmetic products marketed in several colour shades, all colouring agents used in the range may be listed, provided that the terms "may contain" or "+/-" be added.

The ingredients shall be specified using the nomenclature from the latest edition of standard references (Refer to appendix A). Botanicals and extract of botanicals should be identified by its genus and species. The genus may be abbreviated;

The following shall not, however, be regarded as ingredients:

- Impurities in the raw materials used;
- Subsidiary technical materials used in the preparation but not present in the final products;
- Materials used in strictly necessary quantities as solvents, or as carriers, for perfume and aromatic compositions;

- d) Country of manufacture;

- e) The name and address of the company or person responsible for placing the product on the local market;
- f) The contents given by weight or volume, in either metric or both metric and imperial system;
- g) The manufacturer's batch number;
- h) The manufacturing or the expiry date of the product in clear terms (e.g. month/year). The date shall be clearly expressed and shall consist either of the month and year or the day, month and year in that order. The date of minimum durability shall be the date until which this product, stored under appropriate conditions, continues to fulfil its initial function and, in particular, remains in conformity with article 3. It should be preceded by the words "expiry date" or "best before". If necessary, this information shall be supplemented by an indication of the conditions which must be satisfied to guarantee the stated durability.

Indication of the expiry date shall be mandatory for cosmetic products the minimum durability of which is less than 30 months.

- i) Special precautions to be observed in use, especially those listed in the column "Conditions of use and warnings which must be printed on the label in Annexes __", which must appear on the label as well as any special precautionary information on the cosmetic products.

Member countries may require specific warnings based on local needs for declaration of ingredients from animal origin. In this case:

- (i). There must be a statement (of any format) on the product label signalling the presence of ingredients of animal origin;
 - (ii). For ingredients of bovine or porcine origin, the exact animal must be declared;
2. In cases where the size, shape or nature of the container or package does not permit the particulars laid down in paragraphs 1 (a) to (i) to be displayed, the use of leaflets, pamphlets, hang tags, display panel, shrink wrap, etc. shall be allowed. However the following particulars at least shall appear on small immediate packaging:
 - a) The name of the cosmetic product;
 - b) The manufacturer's batch number;
 3. The particulars referred to in paragraphs 1 and 2 shall be easily legible, clearly comprehensible and indelible;
 4. The particulars listed in paragraph 1 shall appear in English and/or National Language and/or a language understood by the consumer where the product is marketed. Member Countries may require that the information in paragraphs (a), (b), (e), (f) and (i) be in the national language or a language easily understood by the consumer;

APPENDIX A

List of Standard References to be used for Cosmetic Ingredient Nomenclature

1. International Cosmetic Ingredient Dictionary;
2. British Pharmacopeia;
3. United States Pharmacopeia;
4. Chemical Abstract Services.

Appendix 4: ASEAN Cosmetic Directive Guidelines for Product Information File (PIF)

GUIDELINES FOR PRODUCT INFORMATION FILE (PIF)

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1. Introduction and Objective

The ASEAN Cosmetic Directive (ACD) requires persons or companies placing a product on the market to keep a product information file "readily accessible to the regulatory authority of the Member State concerned at the address specified on the label in accordance with article 6 of this Directive".

The main objective of this ASEAN Product Information File (PIF) Guideline* is to provide companies placing a cosmetic product in the market recommendations on how to organize and compile the PIF based on a recommended PIF format. This document also provides guidance on who is responsible to keep the PIF and some guiding points for PIF audits.

**This is not a legal document and as such, compliance is not a mandatory requirement.*

2. PIF Organization

2.1 Product Information Required under ACD

Article 8 of the ACD spells out the list of information required in the PIF:

- a) The qualitative and quantitative composition of the product, in case of perfume compositions, the name and code number of the composition and the identity of the supplier;
- b) Specifications of the raw materials and finished product;
- c) The method of manufacture complying with the good manufacturing practice as laid down in the ASEAN Guidelines
- d) Assessment of the safety for human health of the finished product, its ingredients, their chemical structure and level of exposure;
- e) Existing data on undesirable effects on human health resulting from use of the cosmetic product; and
- f) Supporting data for claimed benefits of cosmetic products should be made available; to justify the nature of its effect;

Article 9 of the ACD requires the company to provide information on the method of analysis to the regulatory authority:

- a) The available methods used by the manufacturer to check the ingredients of cosmetic products corresponding with the Certificate of Analysis; and
- b) The criteria used for microbiological control of cosmetic products and chemical purity of ingredients of cosmetic products and/or methods for checking compliance with those criteria"

2.2 Recommended PIF format

In view of the above ACD requirements, companies placing products in the market need to organize the PIF in such a way that it meets the requirements and be easily consulted by the Authorities. It is recommended that the PIF be organised into 4 parts as follows:

- Part I: Administrative Documents and Product Summary
- Part II: Quality Data of Raw Material
- Part III: Quality Data of Finished Product
- Part IV: Safety and Efficacy Data

A Table of Contents should be provided for each of the 4 parts.

Part I: Administrative Documents and Product Summary

The first part of the PIF contains the administrative documents and key summary information that are specific to a single product; i.e. this part would provide an ample overview of the finished product.

- A. Administrative documentation
 - Copy of the Notification form bearing the acknowledgement receipt from the Authorities; this will include the identity of the product, the address of the manufacturer, assembler, importer and company placing the product in the market;
 - Authorisation letter by product owner or agreement letter related to the product, if required by the legislation of the Member Country;
 - Any other relevant administrative documents that may be prescribed by the local Authorities e.g. Licence to Operate, Certificate of Incorporation of the Company;
- B. Qualitative and Quantitative formula of the product (INCI or other ACD approved reference names and corresponding concentrations of the ingredients):
 - For fragrance materials, name and code number of the composition and the identity of the supplier;
- C. Product presentation and label, including:
 - Outer and inner labels (photographs and/or drawings will be useful);
 - Consumer information leaflets and instruction for use if part of the product as sold to the consumer;
- D. Manufacturing Statement:
 - A statement by the manufacturer or company that the product was manufactured according to the ASEAN GMP Guidelines or any ACC approved equivalent GMP Guidelines;
 - Provide the batch coding system/ key of the product;
- E. Safety Assessment (summary) as per the ASEAN Guidelines for the Safety Assessment of a Cosmetic Product:
 - Safety statement (signed statement of opinion, including the name and qualifications of the safety assessor);
- F. Confirmed undesirable effects on human health (summary);
- G. On-pack product claim support (summary):
 - Summary report of the Efficacy Assessment of the product, based on its composition or on tests performed;

Part II: Quality Data of Raw Materials

The second part of the PIF should include full technical information on the quality of the raw materials/ ingredients:

- A. Specifications and test methods of raw material/ ingredients:
 - Specifications of each ingredient including water specification, if appropriate;

- Method of analysis corresponding to the specifications for each ingredient, including identification of the ingredients;
- For fragrance materials, specify the name and code number of the composition, name and address of the supplier, certificate of compliance with the latest IFRA guidelines;

- B. Data on the safety of the raw materials based on data from the supplier, on published data or on reports from Scientific Committees like the ASEAN Cosmetic Scientific Body (ACSB), the EU Scientific Committee on Consumer Products (SCCP) or the US Cosmetic Ingredient Review Board (CIR);

Part III: Quality Data of Finished Product

The third part of the PIF supplies the detailed technical information on the quality of the finished product:

- A. Qualitative and Quantitative formula of the product (INCI or other approved ACD reference names and corresponding concentrations of the ingredients):
 - The formula should specify the functions of each raw material/ ingredient;
- B. Manufacturing:
 - Manufacturer contact details: name, country and address of manufacturer, assembler and packager;
 - Summary of the Manufacturing Process;
 - Additional detailed information on the manufacturing process, quality controls and related manufacturing documents should be made available upon request by the Authority;
- C. Specifications and test methods of the finished product:
 - The criteria used for microbiological control of cosmetic products and chemical purity of ingredients of cosmetic products;
 - Method of Analysis corresponding to the specifications for checking compliance;
- D. Product Stability Summary Report, if the product durability is below 30 months:
 - The stability testing data and report or stability assessment to support the expiry date;

Part IV: Safety and Efficacy Data

The fourth and final part of the PIF provides detailed information on the safety assessment and data of the finished product and also relevant efficacy data to support any claims made on the product.

- A. Safety Assessment:
 - Signed assessment report of the safety for human health of the finished product based on its ingredients, their chemical structure and level of exposure;
 - Curriculum Vitae of the safety assessor;
- B. The latest compiled report on confirmed or recorded adverse events or undesirable effects on human health resulting from use of the cosmetic product:
 - The adverse event report in the PIF is expected to be updated by the company on a regular basis;
- C. On-pack product claim support:
 - Full signed report of the Efficacy Assessment of the product, based on its composition or on tests performed;
 - Supporting data including literature review for claimed benefits of cosmetic products should be made available to justify the nature of its effect;

3. Who is responsible to keep the PIF

Article 8 of the ACD states that the company or person responsible for placing the cosmetic product in the market shall keep the PIF readily accessible to the regulatory authority at the address specified on the label, which, according to the labelling requirements [Appendix II, C (e)] is “the name and address of the company or person placing the product on the local market”. The definition of such has been given in the “Guidance document on product notification to the Regulatory Authority” as “the local company responsible for placing the cosmetic product in the market, which may be a local manufacturer or an agent appointed by a manufacturer to market the product or the company that is responsible for bringing in the product for sale in the country, etc.” This clearly refers to a company or person having an address in the local market, and to the company or person responsible for bringing in the product into that market; whether this is an importer, a manufacturer or a distributor.

It is recommended that the PIF is kept for a minimum period of 3 years after the product is last placed in the market.

4. PIF Audits

4.1 Types of audits:

Since the PIF must be at the address specified on the label, Authorities can audit the PIF at that address. There are 2 possibilities:

- **Routine audits:** The Authorities will announce these audits in advance. It is recommended that the audit be announced sufficiently in advance (i.e. at least 1 month) for the company to prepare for the audit;
- **Ad-hoc audits:** these may be triggered by results found on samples from the market, by consumer complaints, etc. It is recommended that the audit be announced at least 48 hours in advance. Of course, in case of extreme urgency the auditing can take place without announcement;

4.2 Documents to be made readily available:

While the whole PIF should be available, in order to facilitate the preparation of the industry, in particular the SMEs as well as the importers/ distributors, the documents in Part I of the PIF should be made readily available especially for initial investigative audits.

4.3 Documents to be made accessible to Authorities within reasonable time:

Upon specific request from the Authorities, documents, detailed information or reports in other parts of the PIF should be available and made accessible to the Authorities within an agreed upon timeframe: within 15 to 60 calendar days or shorter, depending on the urgency of the audit.

4.4 Background or supplementary documents:

In general the information provided in the PIF should be sufficient for review to ensure “the safety, quality and claimed benefits of all cosmetic products marketed in ASEAN” as specified in article 1(a) of the ASEAN Harmonized Cosmetic Regulatory Scheme.

However, in some specific cases, other background or supplementary information supporting the PIF documents (e.g. product experience, microbiological challenge tests, additional confirmatory test methods, production records, etc.) may be necessary. The company or person responsible for placing the product in the market should then make all efforts to provide the requested information to the Authorities.

4.5 Document media:

There are no specific requirements on what media type the PIF documents should be presented. Hence the company may choose any suitable media i.e. paper, electronic, etc. provided they are convenient and could be easily consulted by the Authorities.

Appendix 5: ASEAN Cosmetic Claims Guidelines

ASEAN COSMETIC CLAIM GUIDELINE

1. Introduction

The evaluation of product claims cannot be separated from the consideration of whether a product is a cosmetic or not. Whether a product can be considered to be a cosmetic product depends on several factors, claims are an important element of this process. This guideline provides a simple 5-step decision-making process that helps to identify products and claims which can be considered to be cosmetics. The document also provides some examples of unacceptable claims for cosmetic products. However, it is not to be taken as the final authority nor as an exhaustive list.

2. Decision Process to identify cosmetic products and allowable claims (See summary chart below)

a. Composition of cosmetics

The product should contain only ingredients that comply with the annexes of ACD, and does not contain any ingredients that are banned in the ACD.

b. Target site of application of cosmetics

The product should be intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity.

Products that are intended to be ingested, injected or placed in contact with other parts of the human body e.g. the mucous membranes of the nasal passage or the internal genitalia cannot be considered to be cosmetic products.

c. Intended main function of cosmetics

The product should be applied to the permitted parts of the human body with a view exclusively or mainly to clean them, perfuming them, changing their appearance and/or correcting body odors and/or protecting them or keeping them in good condition.

Note that products may have a secondary, minor function that is outside the above scope. Some examples of acceptable secondary claim areas are given below. Note that this is not an exhaustive list.

- Dandruff
- Cellulite
- Bust contouring
- Anti-bacterial
- Caries
- Hair loss
- Acne

d. Product presentation of

The product should not be presented as treating or preventing disease in human beings. The following features of the product should be taken into account

- Product claims and the context in which the claims are made
- Labeling and packaging/packaging inserts (including graphics)
- Promotional literature, including testimonials and literature issued by third parties on behalf of the supplier
- Advertisements

- v. The product form and the way it is to be used e.g. capsule, tablet, injection etc.
- vi. Particular target of the marketing information e.g. specific population groups with, or particularly vulnerable to, specific diseases or adverse conditions.

e. Physiological effects of cosmetics

Every product that has an effect on the functioning of the body also has an effect on its metabolism. Cosmetic products typically have effects that are not permanent, and have to be used regularly to maintain their effects.

As a first point of guidance, claims that can be reasonably expected for product types given in the Illustrative List of Cosmetic Products (Appendix 1) can be considered to be cosmetic in nature.

Section 3. below gives some examples of unacceptable claims for cosmetic products. Note that it is not an exhaustive list.

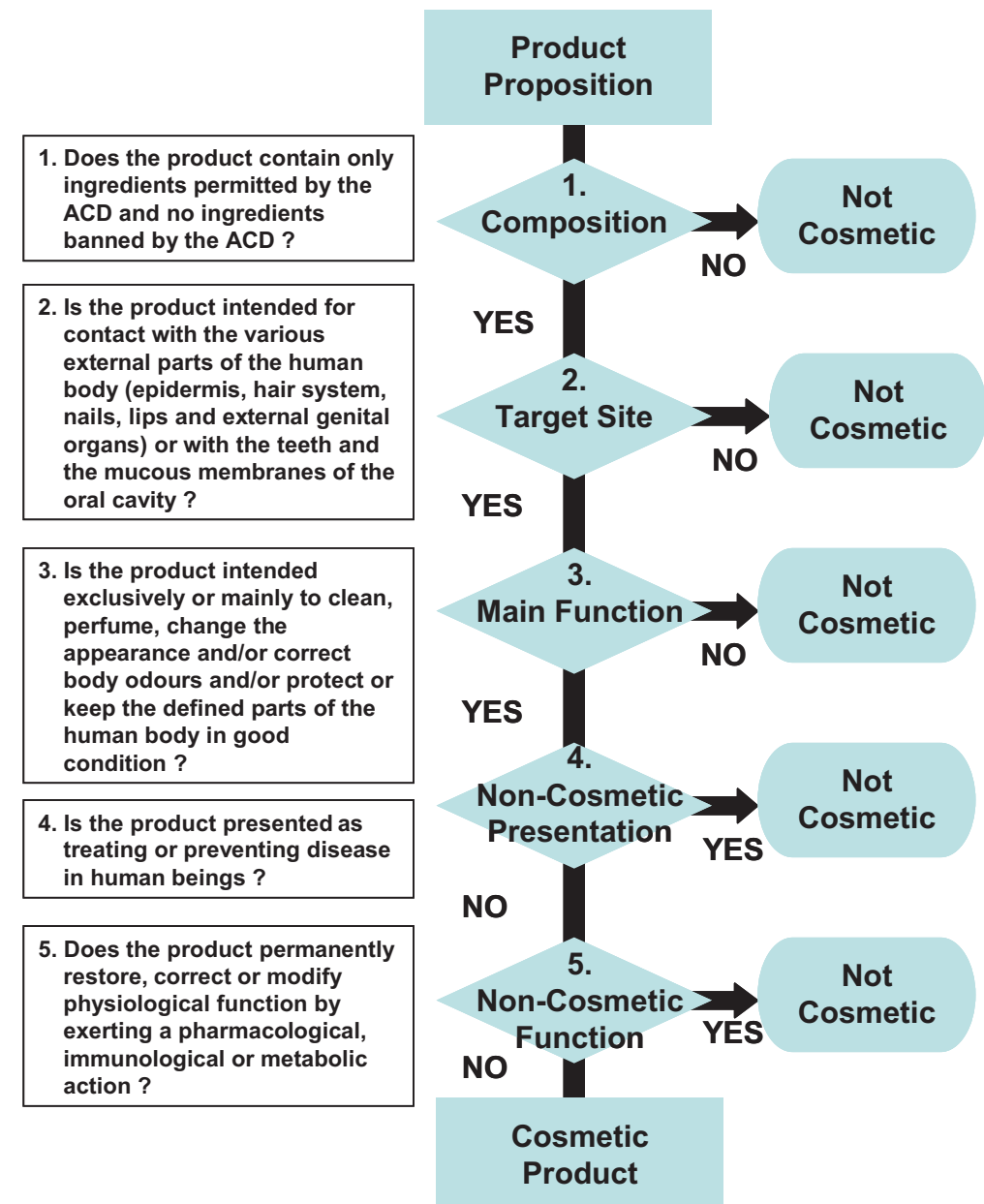
3. Some examples of unacceptable claims commonly observed for cosmetics under the product types.

Product Type	Unacceptable Claims
Hair care products	<ul style="list-style-type: none"> • Eliminates dandruff permanently • Restores hair cells • Hair loss can be arrested or reversed • Stimulates hair growth
Depilatories	<ul style="list-style-type: none"> • Stops/retards/prevents hair growth
Nail products	<ul style="list-style-type: none"> • Reference to growth resulting from nourishment
Skin products	<ul style="list-style-type: none"> • Prevents, reduces or reverses the physiological changes and degeneration conditions brought about by aging • Removes scars • Numbing effect • Prevents, heals, treats or stops acne • Treatment of cellulite • Lose centimetres • Reduces/controls swelling/oedema • Removes/burns fat • Fungicidal action • Virucidal action
Oral or dental hygiene products	<ul style="list-style-type: none"> • Treatment or prevention of dental abscess, gumboils, inflammation, mouth ulcers, periodontitis, pyorrhoea, periodontal disease, stomatitis, thrush or any oral diseases or infections • Whitens tetracycline-induced stains
Deodorants & Anti-perspirants	<ul style="list-style-type: none"> • Completely prevents sweating/perspiration
Perfumes/fragrances/colognes	<ul style="list-style-type: none"> • Aphrodisiac or hormonal attraction

Note that claims can be softened i.e. made less functional and more cosmetic in nature by the use of modifiers. An example of this would be a claim for removing all oil from skin. This claim could be softened as follows,

- Helps to remove oil from skin
- Reduces the shine of oily skin
- Suitable for oily skin types
- Makes your skin feel less oily

Decision process to identify cosmetic products & claims



ASEAN GUIDELINES FOR COSMETIC GOOD MANUFACTURING PRACTICE

PREAMBLE

The GMP Guidelines have been produced to offer assistance to the cosmetic industry in compliance with the provisions of the ASEAN Cosmetic Directive. As this document is particularly intended for cosmetic products, clear delineation from drug or pharmaceutical product GMP should be kept in mind.

The Good Manufacturing Practices presented here is only a general guideline for the manufacturers to develop its own internal quality management system and procedures. The important objective must be met in any case, i.e. the final products must meet the quality standards appropriate to their intended use to assure consumer's health and benefit.

1. INTRODUCTION

The objective of the Cosmetic Good Manufacturing Practice (GMP) guidelines is to ensure that products are consistently manufactured and controlled to the specified quality. It is concerned with all aspects of production and quality control.

1.1 General Consideration

- 1.1.1 In the manufacture of cosmetic products, overall control and monitoring is essential to ensure that the consumer receives products of specified quality.
- 1.1.2 The quality of a product depends on the starting materials, production and quality control processes, building, equipment and personnel involved.

1.2 Quality Management System

- 1.2.1 A quality system should be developed, established and implemented as a means by which stated policies and objectives will be achieved. It should define the organisational structure, functions, responsibilities, procedures, instructions, processes and resources for implementing the quality management.
- 1.2.2 The quality system should be structured and adapted to the company's activities and to the nature of its products and should take into consideration appropriate elements stated in this Guidelines.
- 1.2.3 The quality system operation should ensure that if necessary, samples of starting materials, intermediate, and finished products are taken, tested to determine their release or rejection on the basis of test results and other available evidence related to quality.

2. PERSONNEL

There should be an adequate number of personnel having knowledge, experience, skill and capabilities relevant to their assigned function. They should be in good health and capable of handling the duties assigned to them.

2.1 Organisation, Qualification and Responsibilities

- 2.1.1 The organisational structure of the company shall be such that the production and the quality control sections are headed by different persons, neither of whom shall be responsible to the other.

- 2.1.2 The head of production should be adequately trained and experienced in cosmetic manufacturing.

He should have authority and responsibilities to manage production of products covering operations, equipment, production personnel, production areas and records.

- 2.1.3 The head of quality control should be adequately trained and experienced in the field of quality control. He should be given full authority and responsibility in all quality control duties such as establishment, verification and implementation of all quality control procedures. He should have the authority to designate/assign when appropriate, personnel, to approve starting materials, intermediates, bulk and finished products that meet the specification or to reject those which do not conform to the relevant specification or which were not manufactured in accordance with approved procedures and under the defined conditions.
- 2.1.4 The responsibilities and authority of key personnel should be clearly defined.
- 2.1.5 An adequate number of trained personnel should be appointed to execute direct supervision in each section of the production and the quality control unit.

2.2 Training

- 2.2.1 All personnel directly involved in the manufacturing activities should be appropriately trained in manufacturing operations in accordance to GMP principles. Special attention should be given to training of personnel working with any hazardous materials
- 2.2.2 Training in GMP should be conducted on a continuous basis.
- 2.2.3 Records of training should be maintained and its effectiveness assessed periodically.

3. PREMISES

The premises for manufacturing should be suitably located, designed, constructed and maintained.

- 3.1 Effective measures should be taken to avoid any contamination from the surrounding environment and from pests.
- 3.2 Household products containing non-hazardous materials/ingredients and cosmetic products can share the same premises and equipment provided that due care should be exercised to prevent cross contamination and risk of mix-up.
- 3.3 Painted line, plastic curtain and flexible barrier in the form of rope or tape may be employed to prevent mix-up.
- 3.4 Appropriate changing rooms and facilities should be provided. Toilets should be separated from the production areas to prevent product contamination/cross contamination.
- 3.5 Defined areas should be provided for, wherever possible and applicable:
 - 3.5.1 Materials receiving.

- 3.5.2 Material Sampling
- 3.5.3 Incoming goods and quarantine.
- 3.5.4 Starting materials storage.
- 3.5.5 Weighing and dispensing.
- 3.5.6 Processing.
- 3.5.7 Storage of bulk products.
- 3.5.8 Packaging.
- 3.5.9 Quarantine storage before final release of products.
- 3.5.10 Storage of finished products.
- 3.5.11 Loading and unloading.
- 3.5.12 Laboratories.
- 3.5.13 Equipment washing.
- 3.6 Wall and ceiling, where applicable should be smooth and easy to maintain. The floor in processing areas should have a surface that is easy to clean and sanitise.
- 3.7 Drains should be of adequate size and should have trapped gullies and proper flow. Open channels should be avoided where possible, but if required they should be able to facilitate cleaning and disinfection.
- 3.8 Air intakes and exhausts and associated pipework and ducting, when applicable, should be installed in such a way as to avoid product contamination.
- 3.9 Buildings should be adequately lit and properly ventilated appropriate to the operations.
- 3.10 Pipework, light fittings, ventilation points and other services in manufacturing areas should preferably be installed in such a way as to avoid uncleanable recesses and run outside the processing areas.
- 3.11 Laboratories should preferably be physically separated from the production areas.
- 3.12 Storage areas should be of adequate space provided with suitable lighting, arranged and equipped to allow dry, clean and orderly placement of stored materials and products.
 - 3.12.1 Such areas should be suitable for effective separation of quarantined materials and products. Special and segregated areas should be available for storage of flammable and explosive substances, highly toxic substances, rejected and recalled materials or returned goods.
 - 3.12.2 Where special storage conditions e.g. temperature, humidity and security are required, these should be provided.
 - 3.12.3 Storage arrangements should permit separation of different labels and other printed materials to avoid mix-up.

4. EQUIPMENT

Equipment should be designed and located to suit the production of the product.

4.1 Design and Construction

- 4.1.1 The equipment surfaces coming into contact with any in-process material should not react with or adsorb the materials being processed.
- 4.1.2 Equipment should not adversely affect the product through leaking valves, lubricant drips and through inappropriate modifications or adaptations.
- 4.1.3 Equipment should be easily cleaned.
- 4.1.4 Equipment used for flammable substances should be explosion proof.

4.2 Installation and Location

- 4.2.1 Equipment should be located to avoid congestion and should be properly identified to assure that products do not become admixed or confused with one another.
- 4.2.2 Water, steam and pressure or vacuum lines, where applicable, should be installed so as to be easily accessible during all phases of operation. They should be clearly identified.
- 4.2.3 Support systems such as heating, ventilation, air conditioning, water (such as potable, purified, distilled), steam, compressed air and gases (example nitrogen) should function as designed and identifiable.

4.3 Maintenance

- 4.3.1 Weighing, measuring, testing and recording equipment should be serviced and calibrated regularly. All records should be maintained.

5. SANITATION AND HYGIENE

Sanitation and hygiene should be practised to avoid contamination of the manufacturing of products. It should cover personnel, premises, equipment/apparatus and production materials and containers.

5.1 Personnel

- 5.1.1 Personnel should be healthy to perform their assigned duties. Regular medical examination must be conducted for all production personnel involved with manufacturing processes.
- 5.1.2 Personnel must practise good personal hygiene.
- 5.1.3 Any personnel shown at any time to have an apparent illness or open lesions that may adversely affect the quality of products should not be allowed to handle raw materials, packaging materials, in-process materials, and finished products.

- 5.1.4 Personnel should be instructed and encouraged to report to their immediate supervisor any conditions (plant, equipment or personnel) that they consider may adversely affect the products.
- 5.1.5 Direct physical contact with the product should be avoided to ensure protection of the product from contamination. Personnel should wear protective and clean attire appropriate to the duties they perform.
- 5.1.6 Smoking, eating, drinking and chewing, food, drinks and smoking materials and other materials that might contaminate are not permitted in production, laboratory, storage or other areas where they might adversely affect product quality.
- 5.17 All authorised personnel entering the production areas should practice personal hygiene including proper attire.

5.2 Premises

- 5.2.1 Adequate employee's washing and well ventilated toilet facilities should be provided and separated from the production area.
- 5.2.2 Suitable locker facilities should be provided at appropriate location for the storage of employees' clothing and personal belongings.
- 5.2.3 Waste material should be regularly collected in suitable receptacles for removal to collection points outside the production area.
- 5.2.4 Rodenticides, insecticides, fumigating agents and sanitising materials must not contaminate equipment, raw materials, packaging materials, in-process materials or finished products.

5.3 Equipment and Apparatus

- 5.3.1 Equipment and utensils should be kept clean.
- 5.3.2 Vacuum or wet cleaning methods are preferred. Compressed air and brushes should be used with care and avoided if possible, as they increase the risk of product contamination.
- 5.3.3 Standard operating procedures must be followed for cleaning and sanitising of major machines.

6. PRODUCTION

6.1 Starting Materials

6.1.1 Water

Special attention should be paid to water, since it is an important raw material. Water production equipment and water systems should supply quality water. Water systems should be sanitized according to well-established procedures.

The chemical and microbiological quality of water used in production should be monitored regularly, according to written procedures and any anomaly should be followed by corrective action.

The choice of method for water treatment such as deionisation, distillation or filtration depends on product requirement. The storage as well as delivery system should be properly maintained.

6.1.2 Verification of materials

All deliveries of raw materials and packaging materials should be checked and verified for their conformity to specifications and be traceable to the product.

Samples of raw materials should be physically checked for conformity to specifications prior to release for use. The raw materials should be clearly labelled. All goods must be clean and checked for appropriate protective packing to ensure no leakage, perforation or exposure.

6.1.3 Rejected materials

Deliveries of raw materials that do not comply with specification should be segregated and disposed according to standard operating procedures.

6.2 Batch Numbering System

6.2.1 Every finished product should bear a production identification number which enables the history of the product to be traced.

6.2.2 A batch numbering system should be specific for the product and a particular batch number should not be repeated for the same product in order to avoid confusion.

6.2.3 Whenever possible, the batch number should be printed on the immediate and outer container of the product.

6.2.4 Records of batch number should be maintained.

6.3 Weighing And Measurement

6.3.1 Weighing should be carried out in the defined areas using calibrated equipment.

6.3.2 All weighing and measurement carried out should be recorded and, where applicable, counterchecked.

6.4 Procedure And Processing

6.4.1 All starting materials used should be approved according to specifications.

6.4.2 All manufacturing procedures should be carried out according to written procedures

6.4.3 All required in-process controls should be carried out and recorded.

6.4.4 Bulk products should be properly labelled until approved by Quality Control, where applicable.

6.4.5 Particular attention should be paid to problem of cross-contamination in all stages of processing.

6.5 Dry Products

Handling of dry materials and products should be given special attention. Where possible, dust-containing production system, central vacuum system or other suitable methods should be employed.

6.6 Wet Products

- 6.6.1 Liquids, creams and lotions should be produced in such a way as to protect the product from microbial and other contamination.
- 6.6.2 The use of closed systems of production and transfer is recommended.
- 6.6.3 Where pipe-lines are used for delivery of ingredients or bulk products, care should be taken to ensure that the systems are easy to clean.

6.7 Labelling and Packaging

- 6.7.1 Packaging line should be inspected for clearance prior to operation. Equipment should be clean and functional. All materials and products from previous packaging operation should have been removed.
- 6.7.2 Samples should be taken and checked at random during labelling and packaging operations.
- 6.7.3 Each labelling and packaging line should be clearly identified to avoid mix-up.
- 6.7.4 Excess labels and packaging materials should be returned to store and recorded. Any rejected packaging materials should be disposed off accordingly.

6.8 Finished Product: Quarantine and Delivery to Finished Stock

- 6.8.1 All finished products should be approved by Quality Control prior to release.

7. QUALITY CONTROL

7.1 Introduction

Quality control is an essential part of GMP. It provides assurance that cosmetic products will be of consistent quality appropriate to their intended use.

- 7.1.1 A quality control system should be established to ensure that products contain the correct of specified quality and quantity and are manufactured under proper conditions according to standard operating procedures.
- 7.1.2 Quality control involves sampling, inspecting and testing of starting materials, in process, intermediate, bulk, and finished products. It also includes where applicable, environmental monitoring programs, review of batch documentation, sample retention program, stability studies and maintaining correct specifications of materials and products.

7.2 Reprocessing

- 7.2.1 The methods of reprocessing should be evaluated to ensure that they do not affect the quality of the product.
- 7.2.2 Additional testing of any finished product which has been reprocessed should be performed.

7.3 Returned Products

- 7.3.1 Returned products should be identified and stored separately either in allocated area or by moveable barrier such as rope or tape.
- 7.3.2 All returned products should be tested if necessary, in addition to physical evaluation before being released for distribution.
- 7.3.3 Returned products which do not comply with the original specification should be rejected.
- 7.3.4 Rejected products should be disposed according to appropriate procedures.
- 7.3.5 Records of returned products must be maintained.

8. DOCUMENTATION

8.1 Introduction

The documentation system should include the complete history of each batch, from starting materials to finished products. The system should record executed activities for maintenance, storage, quality control, primary distribution and other specific matters related to GMP.

- 8.1.1 There should be a system for preventing the use of any superseded document.
- 8.1.2 If an error is made or detected on a document, it should be corrected in such a manner that the original entry is not lost and correction is made close to the original entry, initialled and dated.
- 8.1.3 Where documents bear instructions they should be clearly written step by step.
- 8.1.4 Documents should be dated and authorised.
- 8.1.5 Documents should be readily available to relevant parties.

8.2 Specifications

All specifications should be approved by authorised personnel.

- 8.2.1 Raw and packaging material specifications should include :
 - (a) Name of material
 - (b) Description of the material

- (c) Testing parameters and acceptance limits
- (d) Technical drawings, where applicable.
- (e) Special precautions e.g. storage and safety conditions, if necessary.

8.2.2 Bulk and finished product specifications should include:

- (a) Name of product
- (b) Description
- (c) Physical properties
- (d) Chemical assay and/or microbiological assays and their acceptance limits; if necessary
- (e) Storage conditions and safety precautions, if necessary

8.3 Documents for Production

8.3.1 Master Formula

The Master formula should be available upon request. This document should contain the following information:

- (a) Product name and product code/number.
- (b) Intended packaging materials, and storage conditions
- (c) List of raw materials used
- (d) List of equipment used.
- (e) In-process controls with their limits in processing and packaging, where applicable

8.3.2 Batch Manufacturing Record (BMR)

- (a) Batch Manufacturing Records should be prepared for each batch of product.
- (b) Each BMR should include the following :
 - i. Name of product
 - ii. Batch formula
 - iii. Brief manufacturing process
 - iv. Batch or code number
 - v. Date of the start and finish of processing and packaging
 - vi. Identity of individual major equipment and lines or location
 - vii. Records of cleaning of equipment used for processing as appropriate
 - viii. In-process control and laboratory results, such as pH and temperature test records
 - ix. Packaging line clearance inspection records
 - x. Any sampling performed during various steps of processing

- xi. Any investigation of specific failure or discrepancies
- xii. Results of examinations on packed and labelled products

8.3.3 Records for Quality Control

- (a) Records for each testing, assay result and release or rejection of starting materials, intermediates, bulk and finished product should be maintained.
- (b) These records may include :
 - i. Date of test
 - ii. Identification of the material
 - iii. Supplier name
 - iv. Date of receipt
 - v. Original batch number if any
 - vi. Batch number
 - vii. Quality control number
 - viii. Quantity received
 - ix. Date of sampling
 - x. Quality control results

9. INTERNAL AUDITS

An internal audit consists of an examination and assessment of all or part of a quality system with the specific purpose of improving it. An internal audit may be conducted by outside or independent specialists or a team designated by the management for this purpose. Such internal audits may also be extended to suppliers and contractors, if necessary. A report should be made at the completion of each internal audit.

10. STORAGE

10.1 Storage Areas

- 10.1.1 Storage areas should be of sufficient capacity to allow orderly storage of the various categories of materials and products such as starting and packaging materials, intermediates, bulk and finished products, products in quarantine, and released, rejected, returned, or recalled products.
- 10.1.2 Storage areas should be designed or adapted to ensure good storage conditions. They should be clean, dry and well-maintained. Where special storage conditions are required (temperature and humidity) these should be provided, checked and monitored.
- 10.1.3 Receiving and dispatch bays should protect materials and products from weather. Reception areas should be designed and equipped to allow incoming materials to be cleaned if necessary before storage.
- 10.1.4 Storage areas for quarantine products should be clearly demarcated.
- 10.1.5 Wherever possible sampling area for starting materials should be provided to prevent contamination.
- 10.1.6 Hazardous materials should be safely and securely stored.

10.2 Stock Handling and Control

10.2.1 Receiving Products

- 10.2.1.1 Upon receipt, each incoming delivery should be checked against the relevant documentation and physically verified by label description, type and quantity.
- 10.2.1.2 The consignment should be carefully inspected for defects and damage. Records should be retained for each delivery.

10.2.2 Control

- 10.2.2.1 Records should be maintained showing all receipts and issues of products.
- 10.2.2.2 Issues should observe the principle of stock rotation (first in - first out).
- 10.2.2.3 All labels and containers of products should not be altered, tampered or changed.

11. CONTRACT MANUFACTURING AND ANALYSIS

The conditions of contract manufacturing and analysis should be clearly defined, agreed, and controlled so as to avoid misunderstandings, which could result in a product or work of unsatisfactory quality. All aspects of contracted work should be specified to obtain a quality product conforming to the agreed standards.

There should be a written contract between the principal and the contract manufacturer to clearly establish the duties and responsibilities of each party.

12. COMPLAINTS

- 12.1 A person responsible for handling complaints and deciding the measures to be taken should be designated. If this person is different from the authorised person, the latter should be made aware of any complaint, investigation or recall.
- 12.2 There should be written procedures describing the action to be taken, including the need to consider a recall, in the case of a complaint involving a possible product defect.
- 12.3 Complaints involving product defects should be recorded with all the original details and investigated.
- 12.4 If a product defect is discovered or suspected in a batch, consideration should be given to whether other batches should be checked in order to determine whether they are also affected. In particular, other batches that may contain reprocessed product from the defective batch should be investigated.
- 12.5 Where necessary, appropriate follow-up action, possibly including product recall, should be taken after investigation and evaluation of the complaint.
- 12.6 All the decisions and measures taken as a result of a complaint should be recorded and referenced to the corresponding batch records.

12.7 Complaint records should be regularly reviewed for an indication of specific or recurring problems that require attention and might justify the recall of marketed products.

12.8 The competent authority should be informed if a manufacturer is considering action following possibly faulty manufacture and product deterioration, which may lead to serious safety issues.

13. PRODUCT RECALLS

There should be a system of recall from the market of products known or suspected to be defective.

- 13.1 A person responsible for the execution and co-ordination of recalls should be designated, as well as sufficient personnel, to handle all aspects of recalls with the appropriate degree of urgency.
- 13.2 Written procedures for recall should be established and regularly reviewed. Recall operations should be capable of being initiated promptly.
- 13.3 The primary distribution records should be readily available to the person(s) responsible for recalls, and they should contain sufficient information of distributors.
- 13.4 The progress of the recall process should be recorded and a final report issued, including a reconciliation between the delivered and recovered quantities of the products.
- 13.5 The effectiveness of the arrangements for recalls should be evaluated from time to time.
- 13.6 A written instruction should be established to ensure recalled products are stored securely in a segregated area while awaiting decision.

14. GLOSSARY

14.1 Batch

A quantity of any cosmetic product produced in a given cycle of manufacture that is uniform in character and quality.

14.2 Batch Number

A designation in numbers and/or letters or combination of both that identifies the complete history of the batch, quality control and distribution.

14.3 Bulk Product

Any processed product which will have to undergo the packaging operation in order to become a finished product.

14.4 Calibration

Combination of checking an instrument and adjusting it to bring it within its limits for accuracy according to recognized standards.

14.5 Date of Manufacture

Date of manufacturing of a batch of product.

14.6 Documentation

All written procedures, instructions and records involved in the manufacture and quality control of products.

14.7 Product

Any substance or preparation intended to be used, or capable or purported or claimed to be capable of being used, in or for cleansing, improving, altering or beautifying the complexion, skin, hair or teeth.

14.8 Finished Product

A product which has undergone all stages of manufacturing operations.

14.9 In-Process Control

Checks and tests instituted and carried out in the course of the manufacture of a product including checks and tests done on environment and equipment in order to ensure that the end product will comply with its specification.

14.10 Intermediate Product

Any processed substance or mixture of substances which has to undergo one or more stages of processing to become a bulk product.

14.11 Manufacture or Manufacturing

The complete set of activities to produce a product, comprising of production and quality control, from acquisition of all raw materials through processing and subsequent packaging and release for distribution of the finished product.

14.12 Packaging

The part of production cycle applied to a bulk product to obtain the finished product.

14.13 Packaging Material

Any material used in the packaging of a bulk product to obtain the finished product.

14.14 Processing

The part of production cycle starting from weighing of raw materials to obtaining a bulk product.

14.15 Production

All operations starting from processing to packaging to obtain a finished product.

14.16 Quality Control

All measures taken during manufacturing which are designed to ensure the uniform output of product that will conform to established specifications.

14.17 Quarantine

The status of materials or products set apart physically or by system, while awaiting a decision for their rejection or release for processing, packaging or distribution.

14.18 Raw Materials

Any ingredient to be used in the formulation of a cosmetic product.

14.19 Rejected

The status of materials or products which are not permitted to be used for processing, packaging or distribution.

14.20 Released

The status of materials or products which are allowed to be used for processing, packaging or distribution.

14.21 Returned Product

Finished products sent back to the manufacturer.

14.22 Sanitation

Hygienic control on manufacturing premises, personnel, equipment and material handling.

14.23 Specification of Materials

A description of a starting material or finished product in terms of its chemical, physical and biological characteristics, if applicable. A specification normally includes descriptive and numerical clauses stating standards and tolerated deviations.

14.24 Starting Materials

Raw materials and packaging materials used in the production of products.

REFERENCES

Medicines (Cosmetic Products) Regulations 2007

ASEAN Cosmetic Directive

Good Manufacturing Practices for Pharmaceutical Products, World Health Organisation (WHO) Technical Report Series No : 823, 1992

Good Storage Practice, 1st Edition, January 1995, ISBN 983-9870-14-9, National Pharmaceutical Control Bureau, Malaysia

Cosmetic Good Manufacturing Practices, COLIPA – The European Cosmetic Toiletry and Perfumery Association, July 1994

Australian Code of Good Manufacturing Practice for Therapeutic Goods – Sunscreen Products, Therapeutic Goods Administration (TGA), Australia, February 1994

Guidelines on Good Manufacturing Practice (GMP) for Traditional Medicines, National Pharmaceutical Control Bureau, Malaysia, 1st Edition, 1999